Public Health Advisory

Important Information on Chantix (varenicline)

FDA is issuing this public health advisory to alert patients, caregivers, and healthcare professionals to important changes to Chantix prescribing information. Chantix is a medicine used to help patients stop smoking.

At the request of FDA, Pfizer, the manufacturer of Chantix, has updated the Chantix prescribing information to include warnings about the possibility of severe changes in mood and behavior in patients taking Chantix. FDA is highlighting the following related important safety information on Chantix:

- **Patients should tell their doctor about any history of psychiatric illness prior to starting Chantix.** Chantix may cause worsening of a current psychiatric illness even if it is currently under control and may cause an old psychiatric illness to reoccur.
- **Healthcare professionals, patients, patients' families, and caregivers should be alert to and monitor for changes in mood and behavior in patients treated with Chantix.** Symptoms may include anxiety, nervousness, tension, depressed mood, unusual behaviors and thinking about or attempting suicide. **In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of varenicline therapy.**
- **Patients taking Chantix should immediately report changes in mood and behavior to their doctor**.
- **Patients taking Chantix may experience vivid, unusual, or strange dreams.**
- **Patients taking Chantix may experience impairment of the ability to drive or operate heavy machinery.**

While Chantix has demonstrated clear evidence of efficacy, it is important to consider these safety concerns and alert patients that they are possible.

FDA first informed the public about the possibility of severe changes in mood and behavior in the November 20, 2007 *FDA Early Communication About an Ongoing Safety Review*. At that time, information about severe changes in mood and behavior in patients taking Chantix was added to the Chantix label with an explanation that the link between Chantix and these symptoms was unclear. As FDA's review of the data has progressed it has become increasingly likely that the severe changes in mood and behavior may be related to Chantix. As a result, FDA worked

with Pfizer, the manufacturer of Chantix, to add warnings to the Chantix label about the possibility of severe changes in mood and behavior so healthcare professionals and patients can be more alert to this information. In addition, FDA is working with Pfizer to finalize a Medication Guide for patients.

FDA will update the public about any new information from FDA's continuing review of the data or new information that it receives on Chantix and severe changes in mood and behavior. FDA may consider additional changes to the Chantix prescribing information as the data review and conclusions warrant.

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